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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/563,234 | 08/08/2006 | Hazem El-Refaey | BBD.P0022 | 1287 |

7590 05/20/2010

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| EXAMINER | |
|---|---|
| PESELEV, ELLI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/20/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/563,234 | EL-REFAEY, HAZEM | |
| | Examiner | Art Unit | |
| | Elli Peselev | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *40-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerschner et al (U.S. Patent No. 6,899,890) in combination with Herschler (U.S. Patent No. 4,997,823) and Kelly (WO 02/092097).

Kirschner et al disclose a vaginal drug delivery method (column 5, lines 34-44) suitable for delivery of therapeutic drugs. Kirschner et al also disclose that the therapeutically active drug or drugs may be any of those which are used for the treatment of vagina, including antibacterial agents (column 12, lines 62-65) such as azithromycin or metronidazole (column 13, lines 30-31). Kirschner et al further disclose a method of treating vaginal infection (column 114, lines 58-67). However, Kirschner et al do not disclose the administration of an antibiotic in combination with a prostaglandin. However, since an anti-infection composition comprising a combination of prostaglandin and an antibiotic was known in the art at the time of the claimed invention as disclosed by Herschler (column 2, lines 13-60) and vaginal delivery of prostaglandins such as misoprostol (page 6, line 24) was known in the art at the time of the claimed invention as disclosed by Kelly, (page 4, lines 1-2) it would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to administer vaginally a combination of an antibiotic in combination with prostaglandin because such

a person would have expected that the resulting combination would be effective in treating prostaglandin the vagina.

Applicant's arguments filed March 24, 2010 have been fully considered but they are not persuasive.

Applicant contends that claims 40-44 have been amended to indicate that the prostaglandin includes misoprostol and that misoprostol has been shown in the application to produce a synergistic effect in the treatment of pelvic infections and in reducing surgical traumas. This argument has not been found persuasive. In Example 1, a pessary formulation of 500 mg of azithromycin and 400 mcg of misoprostol is set forth. In PILOT STUDY I, azithromycin was administered orally or vaginally at least 18 hours preoperatively to 10 pre-menopausal women undergoinf hysterectomy and TABLE 2 shows tissue concentration of azithromycon achieved. In the PILOT STUDY II, 13 women were administered a pessary formulation of azithromycin and misoprostol 2-4 hours before the surgical pregnancy termination. TABLE 3 shows the concentration of azithromycin achieved. Claims 40 and 44 contain terminology "antibiotic includes azithromycin" and "prostaglandin includes misoprostol" Said terminology encompasses a combination of any antibiotic with azithromycin in any proportion and a combination od anyprostaglandin with misoprostol in any proportion. No data has been presented showing the administration of a combination of antibiotics with a combination of prostaglandins. Claims 56 and 57 encompass administering about 250 to about 1000 milligrams of azithromycin and about 50 to about 1000 milligrams of misoprostol. The data limited to the administration of 500 mg of

azithromcin and 200 mcg or misoprostol is clearly not commensurate with the full scope of the claimed invention. For, example it cannot be ascertained from the data presented if, for example, a combination of 1000 milligrams of azithromycin and 50 milligrams of misoprostol will result in similar azithromycin concentration achieved. Further, the concentration of azithromycin tested in the test data set forth in TABLES 2 and 3 was not tested after the same time interval and the results achieved in different patients appear to vary widely. It is not clear from the data presented how the applicant arrived at he conclusion of synergism. Therefore, the claimed is still deemed prima facie obvious over the cited prior art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623